REMARKS

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed January 28, 2003. Claims 1-9, 11-15 and 21 remain pending. Reconsideration and reexamination in light of the following remarks are respectfully requested.

On page 2 of the Final Office Action, the Examiner rejected claims 1-9, 11-15 and 21 under 35 U.S.C. §102(e) as being anticipated by Heck, U.S. Patent No. 6,083,207. After careful review of the cited reference, Applicants respectfully disagree.

On page 3 of the Final Office Action, the Examiner states that Heck discloses a compressible valve sleeve as element 300. Applicants do not believe that this is an accurate interpretation of the reference. As further explained below, element 300 as disclosed by Heck is not a compressible valve sleeve, and the device disclosed by Heck is not designed to compress element 300.

Claim 1 recites a compressible valve sleeve. Applicants note that the term "compressible" indicates the capacity or ability to be compressed. With respect to the present invention, this should be understood as meaning that within the context of use of the compressible valve sleeve, the compressible valve sleeve may be compressed. It is believed that one of skill in the art would readily understand this definition.

Claim 1 further recites means for compressing said valve sleeve. The means for compressing must be capable of compressing the valve sleeve, and must be provided with sufficient strength or rigidity to perform this function, or must be provided with a shape or other design element for performing the step of compressing the valve sleeve.

In the Advisory Action dated July 10, 2002, the Examiner stated "the medical device disclosed by Heck is considered a compressible valve sleeve, see column 1, lines 13-24, and such

valve sleeve is compressed by element (56), see column 6, lines 43-53." The first cited section states the following:

> There are a number of medical procedures which require the introduction of medical instruments into arteries and veins. In one such procedure, known as the Seldinger procedure, a surgical opening is made in a vein or artery with a needle. A guide wire is then inserted through the lumen of the needle into the vein or artery. The needle is withdrawn leaving the guide wire in place. A dilator is then inserted over the guide wire inside an associated sheath. The dilator and guidewire are removed once the sheath is in place. At this point, various types of catheters or leads may be inserted into the vessel within the lumen of the sheath using the sheath as a conduit to prevent damage to the vessel wall.

Heck at column 1, lines 13-24. Applicants do not see where in this particular passage there is any suggestion of compressing a catheter or a lead. Indeed, looking further into the specification, Heck notes the following:

> One method of preventing, or at least limiting, the flow of blood out of a sheath while a pacemaker lead is being introduced is for the physician to place his thumb over the exposed end of the sheath or to squeeze or pinch the exposed end of the sheath between his thumb and forefinger. However, neither of these methods for reducing the undesired flow of blood and air through the sheath is desirable, because the opportunity for loss of blood and introduction of air is still present. In addition, the structure of these sheaths still requires the surgeon to hold onto it while it is in place in the vessel, thereby limiting the surgeon's ability to perform other medical procedures at the same time. Moreover, squeezing the exposed end of the sheath can deform or even break the sheath, making lead insertion difficult and increasing the likelihood of damage to the lead as it passes through the sheath. Further, even when holding the end of the sheath or pinching the sheath, flow of blood out of the sheath is not entirely stopped.

Column 2, lines 14-32 (emphasis added). It appears that Heck has stated that the sheath and/or lead are not supposed to be compressed and, in fact, compressing them may cause damage. Furthermore, it is well known in the art that many catheters and other device should not be compressed, as this can damage the thin walls of such devices, creating burst risks and the like.

The Examiner also cited the following:

> In addition, by sloping inward toward the lip (56), the inwardly sloped portion (60) of the outside wall (58) provides space for the lips (56) to separate without

> excessive force being applied, as the medical device passes through the lips (56). The inwardly sloped portion (60) of the outside wall (58) preferably slopes at an angle of about 35 to about 75 degrees from the position of the upper portion (62) so that it places pressure on the lip (56) to hold it closed against the corresponding lip of the cooperating hemostasis valve section (40), even when the medical device is forced between the lips (56).

Column 6, lines 43-53 (emphasis added). Again, instead of an indication that the medical device is to be compressed, Heck has stated that the hemostasis valve is provided with a structure specifically designed to protect the medical device against compression. The first underlined portion indicates that the valve described by Heck is provided with a structure to reduce the compression on a medical device. The second underlined portion indicates that a medical device is advanced through the valve lips 56, and does not provide any indication of compression of the medical device.

It should also be noted that Heck has identified the release of fluid through the proximal end of a splittable sheath as the problem to which Heck has directed his invention. If the device 300, which is inserted into the splittable sheath itself, is to be compressed to prevent fluid flow through device 300, then Heck would not be solving the problem he has identified. Fluid flow through the device 300 is not a problem, as the device 300 can be seen to have a hub on its proximal end (Figs. 1-2) which would include a Luer fitting, Tuohy-Borst fitting, or other reversible seal on its proximal end (see Applicants' specification at page 1, lines 20-22). Fluid flow out of the proximal end of the splittable sheath 20 is the problem. The hemostasis valve of Heck is designed to receive and attach to the proximal end of the splittable sheath 20, and provide a fluid seal to that proximal end. Compressing the device 300, which would occur at a location corresponding to valve 14 in Figure 2, as suggested by the Examiner, would not provide any such function.

Looking at Figure 3, the valve 14 prevents fluid flow up from the lower portion of the device past the valve 14 itself. The inclusion of the side port 120 indicates also that fluid is brought up to the chamber 13 of the device shown in Figure 3 as well; otherwise the side port 120 would serve no function. The fluid at that location surrounds any device such as element 300 which is inserted through the valve 14. Pinching element 300 does nothing to prevent this fluid from escaping; instead, the valve 14 must conform around element 300 to securely prevent fluid from flowing past the valve 14.

If Heck intended to pinch off flow through device 300, it would be much easier to simply provide a pinch member made of a rigid metal, rather than including all of the complicated structure shown. Instead of pinching off the device 300, Heck instead teaches the use of materials that will conform to it:

> Each section (38, 40) of the partitioned hemostasis valve (14) is formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber or a foamed rubber of 20 to 60 durometer, which can be shaped to fit within the respective body sections (26, 28) of the partitioned hemostasis valve housing (12).

Column 5, lines 53-59. A pliant, relatively soft material which is resilient would obviously be well suited to performing the function of conforming to, but not pinching, an element passed through the valve 14 of Heck.

In summary, Heck provides no explicit statement or suggestion that element 300 is compressible. Furthermore, compression of element 300 is taught by Heck as potentially damaging the very devices that are to be inserted therethrough. Compressing element 300 is not implicit, implied or necessary for the function of the device of Heck, and would serve no purpose. Heck, in fact, provides a structure specifically designed to avoid compressing element 300 and uses materials that are relatively soft and pliant, though resilient, as typically used in a

hemostasis valve which, as is widely known in the art, does not compress a device advanced therethrough.

In light of the above remarks, Applicants submit that Heck does not disclose or suggest a compressible valve sleeve, which is recited in each of independent claims 1, 3, 12 and 15. Therefore, Applicants believe that each of independent claims 1, 3, 12 and 15 are patentable over Heck. Further, it is believed dependent claims 2, 4-9, 11, 13, 14 and 21 are patentable for the above-stated reasons and because they include further distinct elements not taught by Heck.

Reconsideration and reexamination in light of the above remarks are respectfully requested. Allowance of all pending claims in due course is requested as well. If a telephone conference would be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,
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By their Attorney,

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